DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 5 2004

Medical Intelligence Medizintechnik GmbH
% Mr. Stefan Preiss
510(k) TPR Project Manager
TÜV Product Service, Inc.
1775 Old Highway 8 NW, Suite # 104
NEW BRIGHTON MN 55112

Re: K041448
Trade/Device Name: HexPod™ RT Couch Top
Regulation Number: 21 CFR 892.5770
Regulation Name: Powered radiation therapy patient support assembly
Regulatory Class: II
Product Code: 90 JAI
Dated: May 28, 2004
Received: June 1, 2004

Dear Mr. Preiss:

This letter corrects our substantially equivalent letter of June 16, 2004 regarding the HexPod™ RT Couch Top and the incorrect regulation number, name and product code.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent [(for the indications for use stated in the enclosure)] to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K041448 JUN 16 2004

510(k) SUMMARY

1.	Applicant:	Medical Intelligence Medizintechnik GmbH
2.	Address:	Feyerabendstrasse 13 – 15 86830 Schwabmünchen Germany
3.	Contact Person:	Christian Hieronimi Tel. +49 (0) 8232 9692-0
4.	Preparation Date:	February 10, 2004
5.	Device Submitted:	HexaPOD™ RT Couch Top
6.	Proprietary Name:	HexaPOD™ RT CouchTop
7.	Common Name:	Hexapod
8.	Classification Name:	Couch, Radiation Therapy, Powered Powered radiation therapy patient support assembly Product Code JAI
9.	Substantial Equivalence:	The HexaPOD is substantially equivalent to the following legally marketed devices: Med-Tec Inc.'s "Med-Tec 6 Degree Axis Couch", and Elekta Instrument Inc.'s "Elekta Oncology Systems Precise™ Treatment Table". The characteristics of this device are similar to those of the predicate devices identified on the comparison chart, which is provided with the premarket notification submission. It is our opinion that the HexaPOD does not have technological characteristics that raise additional types of questions related to terms of safety and effectiveness.
10.	Device Description:	The HexaPOD consists of two platforms, which are connected by six linear, rigid but length adjustable elements which are powered. By appropriate coordinative adjustment of these elements, the system is able to move the upper platform relative to the lower one. The movement can occur in all three dimensions in space. Additionally the upper platform can rotate around these three axes which results in a tilt or a rotation of the upper platform relative to the lower one. Finally an accurate positioning within all six degrees of freedom (6DOF) can be provided. The HexaPOD consists of a controller unit which is directed by a cable connected teach pad. Additionally it can be directed via an external graphics user interface (GUI) which is installed on a PC.
11.	Intended Use:	The intended use of the device is to support and aid in positioning a patient during radiation therapy.

12.	Biocompatibility:	The HexaPOD is not in contact with patient. At any time when in use a sheet is to be placed between the patient´s skin surface and the treatment support when in use. Additionally there are no new materials introduced in the manufacture of the HexaPOD. Therefore, no biocompatibility studies were undertaken for this device.
13.	Performance Data:	No performance data is required for this Class II device nor requested by the Food and Drug Administration (Office of Device Evaluation).

Indications for Use

510(k) Number (if known): K041448

Device Name: **HexaPOD™ RT CouchTop**

Indications For Use:

Intended Use: The intended use of the device is to support and aid in positioning a patient during radiation therapy.

Prescription Use _YES_ AND/OR Over-The-Counter Use ___NO___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lepore

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041448